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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: REVISED OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE RE REGISTRATION ELIGIBILITY DECISION DOCUMENT FOR IMAZALIL

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Please find attached the occupational and residential exposure assessment for imazalil

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Executive Summary

This is a revision of the original *Occupational and Residential Exposure Assessment and Recommendations Document for Imazalil*, (S. Tadayon April 15, 2000). This chapter has been revised to correct errors and address comments made by the registrant. The major changes to the assessment include: the revision of the short-term dermal endpoint by HIARC for seed treatment and the removal of the high pressure handwand scenario for citrus fruits. This document presents the occupational exposure assessment for various uses of imazalil. The scope of the assessment covers both WPS (Worker Protection Standard) uses and non WPS uses including post harvest in citrus, seed treatment and egg hatcheries.

Imazalil, [1-(2-(2,4-Dichlorophenyl)-2-(2(propenyloxy) ethyl -1H- Imidazole] is a systemic fungicide used to prevent, treat and control diseases caused by a variety of pathogenic organisms (fungi), which include (but not limited to) Aspergillus in egg handling facilities and equipment, Blue mold in citrus fruits and Fusarium in wheat and barley seeds. **There are no current registered uses for recreational, residential or other public (non-occupational) settings.** The occupational use sites include terrestrial food and feed crop (barley, wheat), terrestrial feed crop (sudangrass), indoor food (post harvest treatment of citrus fruits), and indoor non-food (egg hatching equipment, egg hatching rooms and air ducts). A wide variety of application techniques have been identified that could potentially be used to apply imazalil such as seed treatment, drenchers, smoke generators, fruit waxing equipment and hand held equipment. Imazalil technical grade (98.94 and 98.50 percent active ingredient) is formulated into one impregnated material (14.9 percent active ingredient), 4 liquids (up to 31 percent active ingredient), six emulsifiable concentrates (up to 68.25 percent active ingredient), and a flowable concentrate (10 percent active ingredient).

Acute toxicity categories for the technical grade imazalil are in Toxicity Category II for oral, Toxicity Category III for dermal, and Toxicity Category IV for inhalation. It is in Toxicity Category I for primary eye irritation. The endpoints used in this document to assess imazalil hazards include short- and intermediate-term dermal and inhalation endpoints. A 21-day dermal toxicity study in rabbits was selected for dermal short- term assessment. In this study groups of Albino New Zealand White Rabbits (5/sex/group) received dermal application of imazalil technical grade (98.1% purity) dissolved in sesame oil, 6 hours a day, 5 days a week, for 21 days at doses of 0, 10, 40 or 160 mg/kg to a shaved area on each animal's back At the 160 mg/kg/day dose, erythema was very slight to well defined (Draize score 1-2) and slight to moderate scaling. A 90-day feeding study in rats was used for intermediate-term assessment. The LOAEL for this study is 400 ppm (32.1 and 37.9 mg/kg/day in males and females respectively) and is based on increased absolute liver weights and liver/body weight ratios in males and females at 1 month, possibly increased absolute adrenal weights and adrenal/body weight ratios in females at 3 months, increased centrilobular swollen hepatocytes in males at 1 month, and increased vacuolization in hepatocytes in females at 1 month. The NOAEL in this study is 200 ppm (15.8,and 18.7 mg/kg/day in males and females respectively). A 12-month chronic oral study in dogs was used for long- term dermal assessment. A NOAEL of 2.5 mg/kg/day was selected and is based on clinical signs of vomiting and soft stools, depressed body weight gains, increased

alkaline phosphatase activity and increased liver weights at 20 mg/kg. Since an oral NOAEL was selected, a dermal absorption factor of 41% is used for this risk assessment. A developmental rabbit study was used for short- term inhalation assessment. A NOAEL of 5 mg/kg/day with oral equivalent was selected. A 12 -month chronic oral study in dogs was used for intermediate and long term inhalation exposure. A NOAEL of 2.5 mg/kg/day with oral equivalent was selected. An MOE of 100 used to assess both dermal and inhalation for occupational exposure. There are no residential uses.

The HED carcinogenicity Peer Review Committee (CPRC) met on August 24, 1994 and classified imazalil as a group C (possible human carcinogen) and recommended a linear approach for quantification of risk (see memo dated December 22, 1994). This classification was based on results of a 1993 mouse carcinogenicity study. The registrant subsequently submitted more data and the HED Cancer Assessment Review Committee (CARC) met on July 22, 1998 to consider the new data and issued its report on September 4, 1998 reaffirming the earlier classification of imazalil as a Group C carcinogen. The 23-month carcinogenicity study on mice was evaluated by the HED and concluded that administration of imazalil in the diet to CD-1 mice resulted in statistically significant increases in liver adenomas and adenomas/carcinomas in male Swiss albino mice, with a positive trend for adenomas, carcinomas and combined adenomas/carcinomas. The increase in carcinomas, while not statistically significant by pair wise comparison with controls, was considered by the CPRC to be biologically significant (carcinomas contributed equally to the total response and there was an apparent progression of benign to malignant tumors). Furthermore, the incidence of carcinomas exceeded that of the historical controls submitted by the registrant. In female mice there was only a statistically significant positive trend for liver adenomas and combined adenomas/carcinomas, but the CPRC felt that the tumor response in females was supportive of that seen in males, even though driven mainly by the adenomas. It was also noted that tumors in the mouse appeared at a dose which was not particularly high. Information from structural analogs of imazalil (etaconazole, uniconazole, cyproconazole, tebuconazole) which also induce tumors at the same site (liver) in mice, provided additional support to classify imazalil as a Group C carcinogen. In a subsequent HED memo (Bernice Fisher to Henry Spencer, march 7, 1995), the Q_1^* was estimated to be 6.11×10^{-2} $(mg/kg/day)^{-1}$. On October 27, 1999 the Cancer Assessment Review Committee met to reevaluate the carcinogenic potential of imazalil Under the Draft Guidelines for Carcinogen Risk Assessment (July, 1999), Imazalil is classified in the category **"Likely to be carcinogenic in humans"**. Quantifications of risk have subsequently been estimated. The most potent unit risk will be used for further calculations by the Agency. In this case, the most potent unit risk, Q_1^*, is that for male mouse liver adenoma and/or carcinoma combined tumor rates at 6.11×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents.

The exposure duration for short-term assessments is 1 to 30 days for seed treatment. Intermediate-term durations are greater than 30 days to several months for citrus fruit handlers. Chronic more than 180 days per year for chicken hatcheries have been identified. During the October 24, 2000 meeting HIARC agreed to use short-term NOAEL from a 21-day study for all seed treatment scenarios with exposer duration of less than 30 days.

A **handler** exposure study (seed treatment with lindane) was conducted by Uniroyal on behalf of registrant and submitted to the Agency. These surrogate data, along with other surrogate data available in the Pesticide Handlers Exposure Database (PHED) Version 1.1, were used to assess the potential exposures resulting from mixing, loading and applying imazalil. Potential exposures and internal doses were calculated using unit exposures (i.e., normalized to amount of active ingredient handled mg/lb ai handled). The amount of imazalil assumed handled per day was derived from the various application rates and the number of gallons that could be applied in a single day. Dermal and inhalation margins of exposure (MOEs) are presented.

The results of the short-term dermal assessments (1-30 days assumed) for handlers in seed treatment facilities indicate that the all exposure scenarios provide MOEs greater than or equal to 100 at baseline attire (i.e., long pants, long sleeved shirts, no gloves). The results of the intermediate-term dermal assessments (100 days assumed) for for citrus handlers indicate that the all exposure scenarios provide MOEs greater than or equal to 100 at baseline attire (i.e., long pants, long sleeved shirts, no gloves) except for mixing/loading liquid formulation for waxing equipment (scenario 3). The short, intermediate and long-term inhalation assessment indicates that the all exposure scenarios provide MOEs greater than or equal to 100 at **baseline** attire (i.e, no respirator). The intermediate-term dermal assessments (100 days assumed) for citrus handler indicate that the all exposure scenarios provide MOEs greater than or equal to 100 at **PPE** (i.e., long pants, long sleeved shirts, gloves). All the long-term dermal assessments (250 days assumed) for chicken hatchery handler indicate that the exposure scenarios provide MOEs greater than or equal to 100 at baseline**.**

No **post-application** dermal or inhalation risk assessment was performed for entry following smoke generator or spraying applications in chicken hatcheries. However, based on the low vapor pressure and short half life (118 minutes) of imazalil, HED concludes that ventilation of sufficient duration would adequately mitigate re-entering workers inhalation or dermal following smoke generator applications. Once appropriate ventilation has occurred, HED has no reason to believe that exposures to re-entering would be harmful to hatchery handlers.

Due to the method of seed treatment HED has determined that soil-incorporated," post-application agricultural exposure is considered to be negligible as long as the soil is not directly contacted. The exception is farmers handling treated seed. Therefore it was assumed that exposure to treated seed, which has been stored for an indefinite time before use, represented a minimal exposure hazard to the handler. An estimate of the inherent risk from treated seed was conducted for descriptive purposes using relatively conservative assumptions. The results should be used only for determining a comparative range of exposure. As there are no study data available on exposure to imazalil residue on treated seed, the exposure has been estimated using the unit exposure for handling granular formulations in PHED.

1.0 BACKGROUND

Purpose

In this document, which is for use in EPA's development of the imazalil Reregistration Eligibility Decision Document (RED), EPA presents the results of its review of the potential human health effects of occupational and residential exposure to imazalil.

Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For imazalil, both criteria are met.

1.1 Summary of Toxicity Concerns Relating To Occupational Exposures

Acute Toxicology Categories

Table 1 presents the acute toxicity categories as outlined in the Toxicology Endpoint Selection Document.[1]

Table 1: Acute Toxicity Categories for Imazalil (Technical)

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
870-1100	Acute Oral: Rats	000315964 4107212	LD_{50} = 343 mg/kg LD_{50} = 480-679 mg/kg	II II
870-1200	Acute Dermal: Rabbits	41606104 44107213	LD_{50} = >2000 mg/kg LD_{50} = >2000 mg/kg	III III
870-1300	Acute Inhalation: Rats	44107214	LC_{50} = 2.43 mg/L	IV
870-2400	Primary Eye Irritation	41606105	Irritating	I
870-2500	Primary Skin Irritation	44107216	Mild-irritation	IV
870-2600	Dermal Sensitization	41718701 40271701	Non-sensitizer Non-sensitizer	IV
870-6200	Acute Neurotoxicity	—		

Other Endpoints of Concern

The Report of the Hazard Identification Assessment Review Committee (HIARC) for imazalil, dated June 29, 1999 indicates that there are toxicological endpoints of concern for imazalil. The endpoints used in assessing the risks for imazalil are presented in Table 2.

Table 2: Endpoints for Assessing Occupational Risks for Imazalil

EXPOSURE SCENARIO	DOSE (mg/kg/day)	EFFECT	STUDY	MOE
Dermal Absorption	41% based on a dermal absorption study in male rats			
Short-Term (Dermal)	Dermal NOAEL=160	Skin effects and swollen livers	21 Day Dermal - Rabbit	100
Intermediate-Term (Dermal)	Oral NOAEL=15.8	Severe liver effects	Subchronic Study - Rats	100
Long-Term (Dermal) (Non-cancer)	Oral NOAEL=2.5	Systemic toxicity: vomiting, soft stools, ↓body weight gain, ↑liver weight, ↑alkaline phosphatase	Chronic Toxicity-Dogs	100
Cancer Chronic Dietary	$Q_1^* = 6.11 \times 10^{-2}$ $(mg/kg/day)^{-1}$	Hepatocytic neoplasm	Carcinogenicity Study Mice	NA
Inhalation (Acute)	Not required: acute inhalation is category IV. Acute exposure not likely.			
Inhalation (Short-term)	Oral NOAEL = 5	Increased resorption and decreased fetuses	Developmental-Rabbit Study	100
Inhalation (Intermediate and long term)	Oral NOAEL = 2.5	Systemic toxicity: vomiting, soft stools, ↓body weight gain, ↑liver weight, ↑alkaline phosphatase	Chronic Toxicity-Dogs	100

1.2 Summary of Use Patterns and Formulations

Formulation Types and Percent Active Ingredient

According to the EPA OPP REFS label tracking system, there are 15 active labels, including two technical grade (98.50-98.94 percent active ingredient), one impregnated material (14.9 percent active ingredient), 4 liquids (up to 31 percent active ingredient), seven emulsifiable concentrates (up to 68.25 percent active ingredient), and a flowable concentrate, (10 percent active ingredient). Impregnated material is used in smoke generators.

Table 3 Summery of Active Imazalil Products		
PRODUCT NAME	% ACTIVE INGREDIENT	REG #/FORMULATION
VITAVAX EXTRA	2.00	400-438/IM
CLINAFARM EC	13.80	773-55/EC
CLINAFARM SMOKE GENERATOR	14.90	773-56/FC
DECCOZIL EC-279	68.25	2792-49/EC
DECCOZIL EC-289	22.20	2792-51/EC
NU-ZONE 10ME	10.00	2935-440/EC
GUSTAFSON FLO-PRO IMZ FLOWABLE	31.00	7501-127/ LIQUID
RTU-VITAVAX-EXTRA	1.20	7501-166/ LIQUID
MAGNATE TECHNICAL	98.50	11678-55/ TECHNICAL
FUNGAFLOR TECHNICAL	98.94	43813-2/ TECHNICAL
FUNGAFLOR 500 EC	44.60	43813-6/EC
FECUNDAL 100 EC	9.50	43813-14/EC
MAGNATE 500 EC	44.50	66222-20/EC
NU-ZONE 10ME	10.00	CA91001400/ LIQUID
GUSTAFSON FLO-PRO IMZ FLOWABLE	31.00	ID98001400/ LIQUID

Type of Pesticide/Targeted Pest/Use Sites

Imazalil, [1-(2-(2,4-Dichlorophenyl)-2-(2(propenyloxy) ethyl -1H- Imidazole is a systemic fungicide, used to prevent, treat, control diseases on a variety of pathogenic organisms (fungi), which include (but not limited to) the following: Aspergillus in egg handling facilities and equipment; Blue mold in citrus fruits and Fusarium in wheat and barley.

Registered Use Site and Use Patterns

At this time products containing imazalil are intended for **occupational** use only. No homeowner uses are referenced on any imazalil label reviewed. There are a number of commercial use pattern for imazalil. It is used in commercial and on farm seed treatment of wheat, barley and sudangrass. Of the quantity treated, 37% is done at commercial seed treatment facilities, and 63% is treated in farms. About 2% of the total wheat and barley acreage in the United States are treated with imazalil (use information provided by Janssen Pharmaceutica). Imazalil is also used in the hatchery equipment sanitation program. Hatchery equipment

includes but is not limited to the empty hatchery, cabinets, setters, coolers, storerooms and handling equipment. A second use in hatcheries is for treatment of ventilation ducts to reduce the level of infectious organisms and spores. Imazalil is also used for preservation of citrus fruits after harvest. The percentage of the total fresh citrus crop treated with imazalil is estimated to be 62% (use information provided by Janssen Pharmaceutica).

1.3 Method and Type of Equipment Used for Mixing/Loading/Applying

The flowable concentrate, and emulsifiable concentrate formulation all require mixing with water to the label-specified dilution. This is usually performed by scooping or pouring the formulation into a mixing tank, often of 100 gallons or more in capacity, with mechanical agitation to keep the resulting emulsion homogenized and prevent variations in application strength. Smaller amounts may be handled when applying these formulations either in a high-pressure hand wand, or via a tiller-planter (or seed drill)-mounted system, where smaller total quantities are applied. Large commercial operations, such as seed treatment, may have mechanical, automated, metered pumps which require only connecting the formulation to the pump.

The truck drencher is the common method of drenching citrus fruits. A truck carrying 50-60 bins (900 lbs per bin) parks under a spray manifold that applies imazalil at 900 gallons per minute for 3-4 minutes. The truck driver vacates the cab and manually activates the drenching process. A gate blocks the path of the truck until the 10-minute draining period is satisfied.

For water and wax spray the imazalil solution is metered from a bulk storage tank to the fruit via either a drip or spray system. Brush beds roll the fruit to evenly distribute the fungicide on the surface. A sensor detects fruit throughput and adjust /shuts off the flow of treating solution to correspond with the fruit flow.

Smoke generators/ fogger are used for chicken hatchery equipment. The smoke generator canister is removed from the carton, placed on a noncombustible surface and the wick is lit. The canister will cease to smoke in 60 seconds and the smoke will dissipate and settle on the surface to be treated.

Timing and Frequency of Application

For citrus, imazalil is used for post harvest treatment of citrus fruit only. Citrus fruits for consumption will be treated before being stored in the warehouses. The frequency of applications in hatcheries is difficult to determine since this depends on the sanitation protocol followed by the poultry facility. Some facilities clean the hatcher cabinets every day while others will only use imazalil once a week. It also depends on the number of hatcher cabinets in a facility. For seed treatment, seed will be treated on as needed basis. However, it is industry practice only to treat enough seeds as are needed to be used that season.

1.4 Incident Report

BACKGROUND

The following data bases have been consulted for the poisoning incident data on the active ingredient Imazalil:

1) OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation risk mitigation measures may be suggested.

2) Poison Control Centers - as the result of a data purchase by EPA, OPP received Poison Control Center data covering the years 1993 through 1996 for all pesticides. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from about 65-70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings, involving drugs, household products, pesticides, etc.

3) California Department of Pesticide Regulation - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.

4) National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others.

IMAZALIL REVIEW

I. Incident Data System

Please note that the following cases from the IDS do not have documentation confirming exposure or health effects unless otherwise noted.

Incident#6469-1

One pesticide incident occurred in 1997, which resulted in minor symptoms. Specific

symptoms were not mentioned. No further information on the disposition of the case was reported.

II. Poison Control Center Data - 1993 through 1996

No cases of exposure were reported to Poison Control Centers for the time period 1993 through 1996.

III. California Data - 1982 through 1998

Detailed descriptions of 24 cases submitted to the California Pesticide Illness Surveillance Program (1982-1998) were reviewed. In 3 of these cases, imazalil was used alone or was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. In the first case, a lemon grader/sorter experienced a rash on her neck, face, and eyelids, which also itched. In the second case, a lemon grader/sorter, who was wearing gloves, wiped her face and experienced a rash. The physician was uncertain as to whether the patient had reacted to the chemical or a possible ringworm infection. In the third case, a worker was repairing a washer-waxer hose line when the product spilled onto his hands. He washed his hands for 15 minutes and experienced a rash on his hands the next day.

IV. National Pesticide Telecommunications Network

On the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, imazalil was not reported to be involved in human incidents.

2.0 OCCUPATIONAL EXPOSURES

2.1 Handler Exposures & Assumptions

HED has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with imazalil. Based on the use patterns and potential exposures described above, 13 major exposure scenarios are identified to represent the extent of imazalil uses.

Exposure scenarios include: (1) mixing/loading liquid formulation for on- farm seed treatment, (2) mixing/loading liquid formulation for drenchers application, (3) mixing/loading liquid formulation to support waxing equipment, (4) mixing/loading the liquid formulation to support foaming equipment, (5) mixing/loading liquid formulation for high pressure handwand applications, (6) applying liquid formulation with a drencher, (7) applying liquid formulation in a foamer equipment, (8) applying liquid formulation in a waxing equipment, (9) applying liquid formulation with a high pressure handwand sprayer, (10) handler for commercial seed-treatment equipment, (11) apply/light smoke canisters, (12) mixing/loading and applying liquid with commercial seed-treatment equipment, (13) mixing/loading and applying seed treatment for on-farm seed treatment.

2.1.1 Submitted Studies

Mixer/loader/applicator exposure data for imazalil were required since one or more toxicological criteria had been triggered. Requirements for applicator exposure studies are addressed by Series 875 Group A (formerly Subdivision U of the Pesticide Assessment Guidelines). One handler exposure study and one air monitoring study were submitted by the registrant and are summarized below.

MRID No. - 447315-01. Review of assessment of worker exposure to Commercial Seed Treatment in Seed Treating Plants[2] (Vitavax® 3RS flowable- Canola-Alberta, Canada). During this study, workers were monitored for dermal and inhalation exposure during the loading, application, bagging, sewing, and stacking of Canola seeds treated with Vitavax ® RS Flowable.

In support of the reregistration process for imazalil, UniRoyal submitted a surrogate worker exposure study on behalf of Janssen Pharmaceutica for review by EPA. The test substance is a water-based flowable seed treatement formulation containing three active ingredient, Lindane (48.7 percent), Thiram (6.43 percent), and Carbathin (3.34 percent).

This study was conducted at three seed-treatment plants in Ontario, Canada. The three facilities were representative of large, medium and small seed-treating operations and all sites used different seed treatment equipment. A total of nine replicates were monitored in the study. The guidelines suggests that at least 15 replicates be examined per study. Four of the replicates were categorized as loader/applicators and the remaining five workers were categorized as seed handlers. The sampling period consisted of one 8 hour work day. The maximum application rate for seed treatment of approximately 562 ml (19oz) of formulated product per 25 kg

(55.31lb) seed was applied at each site. Treated seed samples were collected twice at each test site to verify the actual application rate. The study is only partially compliant with OPPTS 875 Group A test guidelines.

Study Results

The geometric mean values obtained from this study had the lowest standard deviation and are presented in Table 4.

Table 4 : Summary of the Exposure values of Canola Seed Treatment to Lindane in Canada		
Scenario	mg/lb ai (no gloves)	mg/lb ai (gloves)
Loader/Applicator (Dermal)	0.36	0.063
Seed Handler (Dermal)	0.015	0.0022
Loader/Applicator (Inhalation)	0.0014	0.0014
Seed Handler (Inhalation)	0.00018	0.00018

On-farm seed treatment is considered to be 63% of the total use of treated seed in the U.S.(use information provided by Janssen Pharmaceutica). The only applicable study available to HED was conducted by Fenske, et al., and published in Arch. Environmental Contamination and Toxicology[3]. Dermal and respiratory exposures of 4 workers during the manual treatment of winter wheat at a commercial wheat farm in South Dakota. A dust formulation containing 18.75 percent lindane , packed in 10 lb bags was applied at the label rate of 2 ounces per bushel of seed. The seed and formulation were mixed with a stick. The rest of the grain is then added and the procedure repeated. The dermal exposure estimated by Fenske, was 10.4 mg/lb ai and inhalation exposure estimate 2.4 μg/lb ai. **Dust formulation by far has a higher potential for exposure than the imazalil emulsifiable concentrate formulations. Since this study was the only source of data available to HED for assessing on farm seed treatment therefore, it was used as a screening level to make an estimation on the risk involved.**

MRID No. - 426034-01. The Assessment of Air Levels of Imazalil (R 23 979) Resulting from Smoke Generator Applications - Volume II - Reentry Protection (Inhalation Exposure)[4]. The study does not appear to have been conducted in accordance with a specific guideline or data requirement, but was submitted in support of reregistration of the pesticide product Clinafarm Smoke Generator®.

The study was conducted in a 33 m^3 experimental room. Five smoke generators were ignited and air concentrations were sampled using impingers at intervals from 30 minutes to 24 hours after release. The application rate used in this study was nearly double the recommended rate: 25 grams per 33 m^3, or 0.758 g/m^3. To sample the air in the experimental room, a glass tube 3 m long with an 8 mm internal diameter (I.D.) was extended into the center of the room. The air in the experimental room was sampled three times at each of five intervals, starting at 30

minutes after smoke generation began (i.e., 0.5h, 2.5h, 4.5h, 6.5h, and 8.5h). An additional sample was collected at 24 hours after initial time (i.e., t = 24h). Each of the three samples in a sampling set were collected sequentially (i.e. for 10 minutes, 10 minutes and 20 minutes - making 40 minutes in all). Each was also collected at different air-flow rates. A half-life of 118 minutes was calculated from this study **No laboratory recovery, fortified sample recovery, or blank analytical data were presented. No sample chromatograms or standard curve data were available for review.** This study is not a true field exposure study. However only portion of the Group B: Postapplication Exposure Monitoring Test Guidelines, 875.2500, Inhalation Exposure Guideline, Small Scale Environmental Chambers does apply to this type of study.

2.1.2 Summary of Occupational Handler Exposures

Table 5 presents the exposure scenarios, application rates (i.e., lb ai/1000ft^3, lb ai/100 gallons, lb ai/100 lb), and amount potentially treated that have been used in the exposure calculations. Imazalil labels include a multitude of uses and a wide range of application rates. Therefore, the rates presented in Table 5 are not all inclusive and an attempt has been made to assess a range of application rates to ensure that all use rates and exposure scenarios are represented.

The above seed treatment exposure data are used in the Agency's assessment to assess the potential handler exposure to imazalil while conducting similar seed treatment activities. PHED[5] V1.1 has also been used to supplement the chemical-specific data and to assess the exposure scenarios which were not monitored by the registrant, however there are a few scenarios that could not be assessed due to a data gap. While data from PHED provides the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration,, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. PHED was designed by a Task Force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates).

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing). Once the data for a given exposure scenario has been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest,

upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

2.1.3 Summary of Uncertainties

The handler exposure assessments encompass all of the major uses of imazalil throughout the country. The assumptions and uncertainties are identified below to be used in risk management decisions:

- *Application Rates:* The application rates are the maximum allowable that were identified on the available product labels. The citrus drencher maximum application rate is assessed at 0.6255 lb/100 gal and wax treatment and foamer at 1.665 lb/100 gal. The seed treatment maximum application rates are 0.006719 lb ai/100 lb for sudangrass, 0.003906 lb ai/100 lb for wheat and barley (mist type seed treater) and 0.01008 lb ai/100 lb for slurry-type seed treater. The egg handling facilities (hatchery and equipment) 0.00032 lb/1000ft^3 for spray and 0.022 lb/1000ft^3 for smoke generator when needed.

- *Amount Handled:* The daily number of gallons mixed for a drencher is assumed to be 1,200 (1,080,000 lbs of citrus) and wax treatment is assumed to be 1,600 (1,440,000 lbs of citrus) gallons per day. For hatcheries the average size of setters 2,520 cubic feet and hatchers 288 cubic feet. A typical hatchery consists of 15 hatchers and 15 setters. For seed treatment Gustafson's seed treaters handle a minimum of 7.5 metric tons/hr to 40.8 metric tons/hr (capacity is based on wheat). For on-farm treatment it was assumed that 100 acres (120 lbs/acre) of wheat and barley can be planted in a day.

- *Unit Exposures:* The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Appendix A Table A5. While data from PHED provides the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases.

- *Data Gap*: No exposure studies were provided by the registrant for drencher, waxing equipment, foaming equipment or smoke generator. For drencher and waxing equipment only a liquid mixer loader scenario was assessed. For smoke generator air concentration was calculated based on maximum application rate at baseline and PPE. For on-farm seed treatment, a published study from Fenske, was used. **Dust formulation by far has a higher potential for exposure than the imazalil emulsifiable concentrate formulations. Since this study was the only source of data available to HED for assessing on farm seed treatment, therefore it was used as a screening level to make an estimation on the risk involved.**

Table 5: Exposure Variables for Uses of Imazalil

Exposure Scenario (Scenario #)	Are Chemical Specific Monitoring Data Available?[a]	Are PHED Data Available?	Application Rates (lb ai/1000ft^3)[b] (lb ai/100 gallons)[b] (lb ai/100 lb)[b]	Daily lb or ft^3 Treated[c]	Daily Gallon Treated[d]
Mixer/Loader Exposure					
(1) mixing/loading liquid formulation for on-farm seed treatment	No	Yes	min 0.003906 lb (0.5 oz) ai/100lb for wheat and barley max 0.01b (1.5 oz) ai/100lb for wheat and barley	12,000	Not Available
(2) mixing/loading liquid formulation for drenchers applications	No	Yes	0.6255 lb ai/100 gallons	1,080,000 lbs	1,200
(3)mixing/loading liquid formulation for waxing equipment	No	Yes	1.665 lb ai/ 100 gallons	1,440,000 lbs	1,600
(4) mixing/loading liquid formulation for foaming equipment	No	Yes	1.665 lb ai/ 100 gallons	Not Available	Not Available
(5) mixing/loading liquid formulation for high pressure hand wand applications	No	Yes	0.00032lb ai/1000ft^3 chicken hatcheries	37800ft^3 setters and 4320ft^3 hatchers	Not available
Applicator					
(6) applying liquid formulation with a drencher	No	No	0.6255 lb ai/100 gallons assumed 1 gal per 900 lbs	1,080,000 lbs	1,200
(7) applying liquid formulation for a foamer equipment	No	No	1.665 lb ai/ 100 gallons	Not Available	Not Available
(8) applying liquid formulation for a waxing equipment	No	No	1.665 lb ai/ 100 gallons	1,440,000 lbs	1,600

Table 5: Exposure Variables for Uses of Imazalil					
Exposure Scenario (Scenario #)	Are Chemical Specific Monitoring Data Available?[a]	Are PHED Data Available?	Application Rates (lb ai/1000ft^3)[b] (lb ai/100 gallons)[b] (lb ai/100 lb)[b]	Daily lb or ft^3 Treated[c]	Daily Gallon Treated[d]
(9) applying liquid formulation with a high pressure handwand sprayer	No	Yes	0.00032lb ai/1000ft^3 chicken hatcheries (½ oz per 150ft^3)	37800ft^3 setters and 4320ft^3 hatchers	Not Available
(10) handler for commercial seed-treatment equipment	No Surrogate data used MRID #447315-01	No	0.006719lb ai/100 lb for Sudangrass (1 oz)	min 132,000 lbs (commercial)	Not Available
				max 718,000 lbs (commercial)	
			min 0.003906 lb (0.5oz) ai/100lb for wheat and barley	min 132,000 lbs (commercial)	
				max 718,000 lbs (commercial)	
			max 0.01b (1.5 oz) ai/100lb for wheat and barley	min 132,000 lbs (commercial)	
				max 718,000 lbs (commercial)	
11) apply/light smoke canisters	No only an air monitoring study available MRID # 426034-01	No	0.022lb/1000ft^3	Not available	Not Available
Mixer/Loader/Applicator					
(12) mixing/loading and applying liquid with a commercial seed-treatment equipment	No Surrogate data used MRID #447315-01	No	0.006719lb ai/100 lb for Sudangrass	min 132,000 lbs (commercial)	Not Available
				Max 718,000 lbs (commercial)	
			min 0.003906 lb (0.5oz) ai/100lb for wheat and barley	min 132,000 lbs (commercial)	
				max 718,000 lbs (commercial)	
			max 0.01b (1.5 oz) ai/100lb for wheat and barley	min 132,000 lbs (commercial)	
				max 718,000 lbs (commercial)	
(13) mixing/loading and applying seed treatment for on- farm seed treatment.	No Surrogate data used Fenske study	No	min 0.003906 lb (0.5oz) ai/100lb for wheat and barley	12,000	Not Available
			max 0.01b (1.5 oz) ai/100lb for wheat and barley		

[a] Surrogate data are available from seed treatment studies (discussed in the text above) and these data are presented in Appendix A Table A4.

[b] Application rates are the maximum labeled rates found on EPA Reg. Nos.400-438, 773-55, 773-56, 2792-49, 2792-51, 2935-440, 7501-127, 7501-166, 11678-55, 43813-2, 43813-6, 43813-14, 66222-20, CA91001400.

[c] Daily amount treated are based on registrant's estimates of lbs of seed or fruit that would be reasonably expected to be treated in a single day for each exposure scenario of concern. The acres planted per day for on farm seed treatment obtained using a planter with 24 rows and 20 feet wide moving at a speed of 5 mph (assumed 120 lbs of wheat or barley planted per acre) planting an average of 100 acres of wheat or barley per day. Commercial seed treatment daily lbs treated was provided by registrant. For citrus drencher it was assumed 20 trucks per day and 1200 gallons of imazalil would be mixed for sprayer

[d] Daily gallons mixed or applied for imazalil

2.1.4 Calculations of Exposure

For passive dosimetry portion of this assessment, potential daily dermal exposure is calculated using the following formula:

Potential daily dermal exposure is calculated using the following formula:

$$\text{Daily Dermal Exposure}\left(\frac{mg\ AI}{Day}\right) = \text{Dermal Unit Exposure}\left(\frac{mg\ AI}{lb\ AI}\right) \cdot \text{Max. Appl. Rate}\left(\frac{lb\ AI}{X}\right) \cdot \text{Max. Amount Treated}\left(\frac{Y}{Day}\right)$$

Where **X** is 1,000 ft^3 or 100 gals or 100 lbs
Where **Y** is ft^3 or gals or lbs

Potential daily inhalation exposure is calculated using the following formula:

$$\text{Daily Inhalation Exposure}\left(\frac{mg\ ai}{day}\right) =$$
$$\text{Unit Exposure}\left(\frac{\mu g\ ai}{lb\ ai}\right) \text{ x Conversion Factor}\left(\frac{1mg}{1{,}000\ \mu g}\right) \text{ x Use Rate}\left(\frac{lb\ ai}{X}\right) \text{ x Daily Amount Treated}\left(\frac{Y}{day}\right)$$

Where **X** is 1,000 ft^3 or 100 gals or 100 lbs
Where **Y** is ft^3 or gals or lbs

These calculations of potential daily exposure to imazalil by handlers are used to calculate the absorbed doses and total risk to those handlers (see *Occupational Risk* section).

2.1.5 Calculation of Cancer

Cancer risk assessments for handler completed by EPA using a baseline exposure scenario and, as needed, increasing levels of risk mitigation (PPE) to achieve cancer risks that are not of concern. Table B in Appendix B present total cancer risk calculations at baseline and with PPE for each exposure scenario.

The calculations of daily dermal and inhalation exposure to imazalil by handlers were used to calculate the daily dose, and hence the risks, to those handlers. Potential daily dermal exposure was calculated using the following formula:

$$\text{Daily Dermal Exposure}\left(\frac{mg\ ai}{day}\right) = \text{Unit Exposure}\left(\frac{mg\ ai}{lb\ ai}\right) \times \text{Use Rate}\left(\frac{lb\ ai}{X}\right) \times \text{Daily Amount Treated}\left(\frac{Y}{day}\right)$$

Where **X** is 1,000 ft^3 or 100 gals or 100 lbs
Where **Y** is ft^3 or gals or lbs

Potential daily inhalation exposure was calculated using the following formula:

$$\text{Daily Inhalation Exposure}\left(\frac{mg\ ai}{day}\right) =$$
$$\text{Unit Exposure}\left(\frac{\mu g\ ai}{lb\ ai}\right) \times \text{Conversion Factor}\left(\frac{1mg}{1{,}000\ \mu g}\right) \times \text{Use Rate}\left(\frac{lb\ ai}{X}\right) \times \text{Daily Amount Treated}\left(\frac{Y}{day}\right)$$

Where **X** is 1,000 ft^3 or 100 gals or 100 lbs
Where **Y** is ft^3 or gals or lbs

The daily dermal and inhalation doses were calculated using a 70 kg body weight using the following formulas:

$$\text{Daily Inhalation Dose}\left(\frac{mg\ ai}{kg/day}\right) = \text{Daily Inhalation Exposure}\left(\frac{mg\ ai}{day}\right) \times \left(\frac{1}{\text{Body Weight (kg)}}\right)$$

$$\text{Daily Dermal Dose}\left(\frac{mg\ ai}{Kg/Day}\right) = \text{Daily Dermal Exposure}\left(\frac{mg\ ai}{Day}\right) \times \left(\frac{1}{\text{Body Weight (Kg)}}\right) \times 0.41\ \text{Dermal Absorption Factor}$$

$$\text{Total Daily Dose} = \text{Daily Dermal Dose}\left(\frac{mg}{kg/day}\right) + \text{Daily Inhalation Dose}\left(\frac{mg}{kg/day}\right)$$

The lifetime average daily dose (LADD) was calculated using the following formula:

$$\text{LADD}\left(\frac{mg}{kg/day}\right) = \text{Daily Total Dose}\left(\frac{mg}{kg/day}\right) \times \left(\frac{\text{days worked}}{365\ \text{days per year}}\right) \times \left(\frac{35\ \text{years worked}}{70\ \text{year lifetime}}\right)$$

Total cancer risk was calculated using the following formula:

$$Total\ Cancer\ Risk = LADD\ x\ Q1^{*}$$

where $Q_1^* = 6.11x10^{-2}\ (mg/kg/day)^{-1}$

The following assumptions and factors were used in order to complete this cancer risk assessment:

- The average body weight of 70 kg is used, representing a typical adult.
- Exposure duration is assumed to be 35 years. This represents a typical working lifetime.
- Lifetime is assumed to be 70 years.
- The $Q1^*$ used in the cancer assessment was $6.11x10^{-2}(mg/kg/day)^{-1}$.
- exposure frequencies used in the calculations are, 250 days for chicken hatcheries (based on the visit to Allen hatcheries in MD), 15 days for commercial seed treatment,10 days on farm seed treatment, and 100 days for commercial citrus applicator.

2.1.6 Calculations of Air Concentration and Risk

Since there was no exposure data submitted by the registrant for smoke generators used in chicken hatchery, the air concentration was calculated at the maximum application rate. It was assumed that the handlers were exposed to the smoke generator for a period of one minute. This time period is an estimate based on the label language. It should be noted, however, that smoke may persist in the air after the canister has ceased to smoke. This effect would be minimized by dilution of smoke from the ventilation system and by the fact that the handlers should vacate the setters or hatchers after lighting the smoke generator. The daily dose was calculated both at the baseline (no respirator) and PPE level (organic vapor respirator).

Each canister contains 5 grams of imazalil and treats $500ft^3$.

$$Air\ Concentration = \frac{5g}{500\,ft^3} \times \frac{1000\,mg}{1g} \times \frac{1\,ft^3}{28.3l}$$

$$Air\ Concentration = 0.35\frac{mg}{l}$$

Inhalation potential dose rates are calculated:

$$PDR = C_a \times IR \times Exposure\ Duration$$

PDR = Potential dose rate (mg/day)
C_a = airborne concentration of imazalil in air
IR = inhalation rate (16.6 l/min)
assuming the applicator is exposed for 1 minute to smoke generator
Short- term Inhalation NOAEL is 5 mg/kg/day
Intermediate and long-term NOAEL is 2.5mg/kg/day
For cancer $Q^* = 6.11 \times 10^{-2}$ $(mg/kg/day)^{-1}$ and 250 days of exposure
The risk from smoke generator at the maximum application rate is summarized in Table 6.

Table 6: Occupational Handler Short, Intermediate and Long-term inhalation Risk from smoke generator containing Imazalil

Scenario[a]	PF	Air concentration (mg/l)[b]	Short-term Dose[c]	Intermediate-long-term Dose[d]	Short-term MOEs[e]	Intermediate, Long-term MOEs[f]	LADD[g]	Cancer[h]
Smoke generator (baseline)	1 (no respirator)	0.35	0.097	0.083	50	30	2.80e-02	1.7e-03
Smoke generator (PPE)	10 (organic vapor respirator)	0.035	0.0097	0.0083	500	300	2.80e-03	1.7e-04

[a] Baseline represents the use of smoke generator without a respirator
PPE represents the use of smoke generator with an organic vapor respirator

[b] See above calculations

[c] Short-term inhalation dose (mg/kg/day) = airborne concentration of imazalil *inhalation rate (16.6 l/min)/body weight (60kg)

[d] Intermediate-long-term inhalation dose (mg/kg/day) = airborne concentration of imazalil *inhalation rate (16.6 l/min)/body weight (70kg)

[e] Short-term Inhalation MOE = NOAEL (5 mg/kg/day)/ Short-term Daily Inhalation Dose (mg/kg/day).

[f] Intermediate-long-term Inhalation MOE = NOAEL (2.5 mg/kg/day)/ Intermediate-term Daily Inhalation Dose (mg/kg/day).

[g] LADD (mg/kg/day) = Daily Dose (mg/kg/day) * (Number of days exposure per year (250)) /365 days per year) * 35 years worked/70 year lifetime.

[h] Cancer Risk = LADD (mg/kg/day) * (Q_1*), where $Q_1^* = 6.11e^{-2}$ (mg/kg/day).

2.2 Risk From Handler Exposures

Using the daily dermal exposure scenarios identified in the exposure section, EPA calculated the potential risk to persons from handler exposures and post-application exposures to imazalil.
Potential dermal and inhalation daily exposures for occupational handlers were calculated using the following formulas (**41 percent dermal absorption was assumed for intermediate and long-term duration**):

$$\text{Daily Inhalation Exposure}\left(\frac{mg\ ai}{day}\right) = \text{Unit Exposure}\left(\frac{\mu g\ ai}{lb\ ai}\right) \times \text{Conversion Factor}\left(\frac{1mg}{1{,}000\ \mu g}\right) \times \text{Use Rate}\left(\frac{lb\ ai}{X}\right) \times \text{Daily Amount Treated}\left(\frac{Y}{day}\right)$$

Where **X** is 1,000 ft^3 or 100 gals or 100 lbs
Where **Y** is ft^3 or gals or lbs

$$\text{Daily Dermal Exposure}\left(\frac{mg\ AI}{Day}\right) = \text{Dermal Unit Exposure}\left(\frac{mg\ AI}{lb\ AI}\right) \cdot \text{Max. Appl. Rate}\left(\frac{lb\ AI}{X}\right) \cdot \text{Max. Amount Treated}\left(\frac{Y}{Day}\right)$$

Where **X** is 1,000 ft^3 or 100 gals or 100 lbs
Where **Y** is ft^3 or gals or lbs

The inhalation and dermal daily doses were calculated using the following formulas:

$$\text{Daily Inhalation Dose}\left(\frac{mg\ ai}{kg/day}\right) = \text{Daily Inhalation Exposure}\left(\frac{mg\ ai}{day}\right) \times \left(\frac{1}{\text{Body Weight (kg)}}\right) * 1\ (100\%)$$

$$\text{Daily Dermal Dose}\left(\frac{mg\ ai}{kg/Day}\right) = \text{Daily Dermal Exposure}\left(\frac{mg\ ai}{Day}\right) \times \left(\frac{1}{\text{Body Weight (kg)}}\right) * 0.41\ (41\%)$$

The MOEs were calculated using the following formulas:

$$MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{\text{Dermal Daily Dose}\left(\frac{mg}{kg/day}\right)}$$

$$MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Inhlation\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

2.2.1 Risk From Handler Exposures

Dermal MOEs were calculated for handlers for short-term duration (up to 30 days), intermediate-term (up to 180 days) durations and long-term (over 180 days). Inhalation MOEs were also calculated for handlers for short-term short-term duration (up to 30 days), intermediate-term (up to 180 days) durations and long-term (over 180 days).

Appendix A tables A1 and A3 presents the exposure calculations at the baseline and for personal protective equipment (PPE). Appendix A tables A2 and A4 presents the MOEs calculations at the baseline and for personal protective equipment (PPE).

HED calculated the **baseline** MOE for each occupational exposure scenario using the following assumption:

- all occupational handlers are wearing long pants, long sleeve shirt and no gloves

If the baseline MOE was 100 or greater (the NOAEL is based on data from animal studies, and therefore, a 10x is applied for both inter species and intra species variations) for an exposure scenario, then no further calculations were made. If the baseline MOE remained less than 100 for any occupational exposure scenario, an addition MOE was calculated based on mandatory use of PPE where feasible. HED calculated the PPE MOE for each occupational exposure scenario with a baseline MOE of less than 100.

2.2.2 Summary of MOEs and Cancer

Table 7 summarizes the MOE values for both the short, intermediate and long -term dermal and inhalation exposure along with cancer risk for occupational handlers. The MOEs are presented for both baseline and PPE. Baseline represents exposure while wearing long pants, long sleeved shirts and no gloves, while using open mixing/loading systems. The PPE represent exposure while wearing long pants, long sleeved shirts and gloves.

The results of the **short-term** dermal exposure duration for seed treatment indicate that the MOEs range from 4.33E +02 to 1.45E+05 . A total of 14 MOEs were calculated for the various application rates assessed in each scenario. Based on the minimum level of protection all of the MOEs are greater than 100. The results of the **short-term** inhalation exposure duration for seed treatment indicate that the MOEs range from 2.98E+3 to 5.33E+05 A total of 14 MOEs were calculated for the various application rates

assessed in each scenario. Based on the minimum level of protection all of the MOEs are greater than 100.

The results of the **intermediate-term** dermal exposure duration for citrus handlers indicate that the MOEs range from 3.5E+1 to 4.52E+3. A total of 2 MOEs were calculated. Based on the minimum level (gloves only) of protection all of the MOEs are greater than 100. The results of the **intermediate-term** inhalation exposure duration for citrus handlers indicate that the MOEs range from 5.46E+3 to 1.94E+04

The results of the **long-term** dermal exposure duration for egg hatchery handlers indicate that the MOEs range from 1.22E +4 to 1.72E+5 . A total of 4 MOEs were calculated. Based on the minimum level of protection all of the MOEs are greater than 100. The results of the **long-term** inhalation exposure duration for egg hatchery handlers indicate that the MOEs range from 1.83E+4 to 1.21E+7 A total of 4 MOEs were calculated. Based on the minimum level of protection all of the MOEs are greater than 100.

The calculations indicate that cancer risks at **baseline** are in the range of 3.80E-03 to 3.36E-07 and Cancer risks with additional **PPE** are in the range of 5.84E-4 to 1.37E-07 for all the scenarios.

Table 7: Summary of Exposure Variables, MOEs and Cancer for uses of Imazalil														
Exposure Scenario (Scenario #)	Range of Application Rates (lb ai/A)	Amount Handled per Day	Short-Term Dermal MOEs		Intermediate-Term MOEs		Long-term MOEs		Short-Term Inhalation MOEs		Intermediate, Long-Term MOEs		Cancer	
			Base line	PPE	Base line	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE
Mixer/Loader														
Mixing/loading liquid formulation for on farm seed treatment (1)	0.003906 lb/100 lb	12,000	8.25e+03	NA	NA	NA	NA	NA	5.33e+05	NA	NA	NA	1.63e-05 2.44e-05	1.37e-07 2.05e-07
	0.01 lb/100 lbs		3.20e+03	NA	NA	NA	NA	NA	2.08e+05	NA	NA	NA	4.16e-05 6.24e-05	3.50e-07 5.25e-07
Mixing/loading liquid (EC) for Drencher application (2)	0.6255 lb ai/100 gallons	1,200 gallons	NA	NA	1.24e+02	NA	NA	NA	NA	NA	1.94e+04	NA	1.07e-03	9.55e-06
Mixing/loading liquid (EC) for a waxing equipment (3)	1.665 lb ai/100 gallons	1,600 gallons	NA	NA	3.48e+01	4.52e+03	NA	NA	NA	NA	5.46e+03	NA	3.80e-03	3.40e-05
Mixing/loading Liquid (EC) for a foaming equipment (4)	1.665 lb ai/100 gallons	No Data	NA	NA	No Data	No Data	NA	NA	NA	NA	No Data	No Data	No Data	No Data
Mixing/loading liquid formulation for high pressure hand application (5)	0.00032 lb ai/1000 ft^3	4320ft^3	NA	NA	NA	NA	1.06e+05	NA	NA	NA	1.05e+07	NA	4.92e-07	NA
		37800 ft^3	NA	NA	NA	NA	1.22e+04	NA	NA	NA	1.21e+07	NA	4.30e-06	NA
Applicator														
Applying liquid formulation with a drencher (6)	0.6255 lb ai/100 gallons	1,200 gallons	NA	NA	No Data	No Data	NA	NA	NA	NA	No Data	No Data	No Data	No Data
Applying liquid formulation for a foaming equipment (7)	1.665 lb ai/100 gallons	1,600 gallons	NA	NA	No Data	No Data	NA	NA	NA	NA	No Data	No Data	No Data	No Data

Table 7: Summary of Exposure Variables, MOEs and Cancer for uses of Imazalil														
Exposure Scenario (Scenario #)	Range of Application Rates (lb ai/A)	Amount Handled per Day	Short-Term Dermal MOEs		Intermediate-Term MOEs		Long-term MOEs		Short-Term Inhalation MOEs		Intermediate, Long-Term MOEs		Cancer	
			Base line	PPE	Base line	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE
Applying liquid formulation for a waxing equipment (8)	1.665 lb ai/100 gallons	No Data	NA	NA	No Data	No Data	NA	NA	NA	NA	No Data	No Data	No Data	No Data
Applying liquid formulation with a high pressure handwand sprayer (9)	0.00032 lb ai/1000 ft^3	4320 ft^3	NA	NA	NA	NA	1.72+05	NA	NA	NA	1.61e+05	NA	3.36e-07	NA
		37800 ft^3	NA	NA	NA	NA	1.95e+04	NA	NA	NA	1.83e+04	NA	2.95e-06	NA
Handler for commercial seed treatment (10)	0.00671 lb ai/100 lbs Sudangrass	132,000	8.43e+04	NA	NA	NA	NA	NA	1.88e+05	NA	NA	NA	2.42e-06	3.83-07
		718,000	1.55e+04	NA	NA	NA	NA	NA	3.46e+04	NA	NA	NA	1.31e-05	2.08e-06
	Min 0.00396 lb ai/100lb wheat and barley	132,000	1.45e+05	NA	NA	NA	NA	NA	3.23e+05	NA	NA	NA	1.35e-06	2.23e-07
		718,000	2.66e+04	NA	NA	NA	NA	NA	5.94e+04	NA	NA	NA	7.66e-06	1.21e-06
	Max 0.01lb ai/100 lbs wheat and barley	132,000	5.66e+04	NA	NA	NA	NA	NA	1.26e+05	NA	NA	NA	3.60e-06	5.71e-07
		718,000	1.04e+05	NA	NA	NA	NA	NA	2.32e+04	NA	NA	NA	2.20e-06	3.10e-06
Apply/light smoke canisters (11)	0.022 lb ai/1000 ft^3	No Data	NA	NA	NA	NA	No Data	No Data	NA	NA	No Data	No Data	No Data	No Data
Mixer/ Loader/Applicator														
Mixing/loading and applying liquid with a commercial seed-treatment equipment (12)	0.00671 lb ai/100 lbs Sudangrass	132,000	3.51e+03	NA	NA	NA	NA	NA	2.42e+04	NA	NA	NA	5.74e-05	1.03e-05
		718,000	6.46e+02	NA	NA	NA	NA	NA	4.45e+03	NA	NA	NA	3.14e-04	5.58e-05

Table 7: Summary of Exposure Variables, MOEs and Cancer for uses of Imazalil														
Exposure Scenario (Scenario #)	Range of Application Rates (lb ai/A)	Amount Handled per Day	Short-Term Dermal MOEs		Intermediate-Term MOEs		Long-term MOEs		Short-Term Inhalation MOEs		Intermediate, Long-Term MOEs		Cancer	
			Base line	PPE	Base line	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE	Baseline	PPE
	Min 0.00396 lb ai/100lb wheat and barley	132,000	6.03e+03	NA	NA	NA	NA	NA	4.15e+04	NA	NA	NA	3.35e-05	5.98e-05
		718,000	1.11e+03	NA	NA	NA	NA	NA	7.63e+03	NA	NA	NA	1.82e-04	3.25e-05
	Max 0.01lb ai/100 lbs wheat and barley	132,000	2.36e+03	NA	NA	NA	NA	NA	1.62e+04	NA	NA	NA	8.56e-05	1.53e-05
		718,000	4.33e+02	NA	NA	NA	NA	NA	2.98e+03	NA	NA	NA	4.66e-04	8.32e-05
Mixing/loading/ applying seed treatment for on-farm seed treatment (13)	0.003906 lb/100 lb	12,000	See PPE	2.30e+03	NA	NA	NA	NA	See PPE	2.65e+05	NA	NA	See PPE	5.84e-05 8.75e-05
	0.01 lb/100 lbs		See PPE	8.96e+02	NA	NA	NA	NA	See PPE	1.04e+05	NA	NA	See PPE	1.50e-04 2.25e-04

See footnotes in appendix A

2.2.3 Insufficient Data

HED has insufficient exposure data to provide an assessment of citrus treatment applications (drencher, wax application and foamers). The current mixer/loader surrogate data from PHED was used to address part of this assessment but there is a possible spray drift to workers from using a drencher. The exposure to applicators from waxing and foaming equipment is minimal since these equipment are operated remotely, however the possibility of exposure to the operator needing to enter the area to monitor the operation of the machinery or fix problems which could occur with the machinery still exists. The air monitoring study submitted by the registrant would not address the exposure resulting from the use of a smoke generator in chicken hatcheries and consequently could not be used in this assessment. For smoke generators, a worst case calculation based on the maximum application rate revealed that in order to obtain the target MOE of 100 an organic vapor respirator would be required. For commercial seed treatment, surrogate data was submitted by Uniroyal on behalf of Janssen pharmaceutica in which the assessment is included, but for on-farm seed treatment, the **only** source of data available was a published study by Fenske which utilized a dust formulation which by far has a higher potential for exposure than the imazalil emulsifiable concentrate formulations. HED welcomes a study utilizing the liquid formulation of imazalil for the on-farm seed treatment, but lacking this data, HED has no other choice but to use Fenske's data to assess for this scenario.

Finally, there are possible dermal and inhalation exposures to handlers applying imazalil to air ducts. No chemical-specific or surrogate data are available to assess handler exposure from this specialized use pattern. The Agency estimates that handler dermal and inhalation exposure would be minimal, since the product is diluted with the flow of air current. Even with a vapor pressure of 1.87E-8 mm Hg, the inhalation exposure should be minimal and relatively small amounts of active ingredient are handled per day. Consequently, in lieu of exposure data upon which to assess risk, EPA will require handlers to wear gloves in addition to baseline attire while handling/applying imazalil. Also for the prevention of spray drift from drenching a glass shield is recommended to prevent any possible dermal and inhalation exposure.

3.0 POSTAPPLICATION EXPOSURES

EPA has determined that there is potential exposure to persons handling citrus fruits after application is complete. The Agency has no data addressing the exposure from post application of citrus with imazalil. The main activities are sorting/culling/ or packing of products following wax treatment. The estimates of exposure were derived from residue chemistry data, surface area calculations, and a reentry study for citrus found in the scientific literature.

3.1 Postapplication Exposures & Assumptions

3.1.1 Published Study

The following is a DFR study used for the calculation of hand transfer coefficient.
Dermal exposure of ten harvesters to chlorbenzilate[6] was monitored in a mature block of "Valencia" orange trees. The pesticide was applied using an airblast equipment at the maximum label rate of 2.5 lbs ai per acre in 200 gallons of water. The ten harvesters wore cotton shirts with exposure pads pinned inside on both shoulders, chest, back, both forearms, and both upper arms. Thigh and shin pads were taped outside the work clothing. Hand exposures were monitored by hand rinse with 95 percent ethanol. Only the handwash data were used for the estimation of thiabendazole exposure to sorters and packers on an assembly line. Dislodgeable foliar and fruit residues were collected on days 1,2,3,4, and 7 after treatment. The dislodgeable residues on fruit remained fairly constant on days 1 to 3, followed by a large decrease on day 4. Exposure data were only presented for days 2, 3, and 4 and only the data from days 2 and 3 were used for estimation of imazalil exposure. The exposures of the hands are presented in the Table 8.

Table 8: Exposure (μg/h) of the hands of workers harvesting citrus 2 and 3 days after application

Replicate	1	2	3	4	5	6	7	8	9	10	Total	Mean
2nd day	40	58	227	37	85	210	953	33	159	54	186	185
3rd day	169	98	170	39	36	42	1050	71	70	89	183	

The resulting transfer coefficient **for the hands only** would be:

Average dislodgeable residues for the 2nd day and 3rd day is 0.12 µg/cm².
Transfer Coefficient, Tc (cm²/hr) = 185 µg/hr ÷ 0.12 µg/cm² = 1500 cm²/hr

The estimated residues on the surfaces of treated citrus were estimated using the following assumptions:

1) A "standard" orange has a diameter of 2¾ inches (~7 cm) and weighs 138 grams.[8]
2) The residue level in an orange or other citrus fruits 2.08 ppm (µg/g). This was obtained from the highest average field trial (HAFT) for orange[7].

3) All of the imazalil in an orange is located on the surface.

4) Workers are assumed to perform the sorting/culling tasks for 8 hours per day.

The amount of imazalil in an orange would be:

Imazalil (µg/orange) =2.08 µg/g x 138 g/orange = 287 µg

1) The surface area of a sphere can be calculated:

Surface Area $=4\pi R^2$
Surface Area = 4 x 3.14 x (7/2 cm)² = 154 cm²

The residue value for imazalil would therefore be:
287 µg/154 cm² = 1.9 µg/cm²

3.2 Risk From Postapplication Exposures

Hand Dermal Exposure (µg/kg/day) =1500 cm²/hr x 1.9 µg/cm² x 8 hrs/day ÷ 70 kg (body weight) x 0.41 (dermal absorption factor)

Hand Dermal Exposure (µg/kg/day) =133 µg/kg/day = 0.133 mg/kg/day

Table 9: Imazalil Intermediate-term and Q*Occupational post application assessment for citrus (waxing only)

Scenario[a]	Dermal Dose[b] (mg/kg/day)	Intermediate -term MOEs[c]	LADD[d]	Cancer[e]
Baseline	0.133	120	1.09e-02	6.68e-04
PPE	0.0133	NA	1.09e-03	6.68e-05

[a] Baseline represents long pants, long sleeved shirt and no gloves
PPE represents long pants, long sleeved shirt and gloves

[b] Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg) x dermal absorption factor (41%) .

[c] Intermediate-term Dermal MOE = NOAEL (15.8 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).

[d] Baseline LADD (mg/kg/day) = Baseline Daily Dose (mg/kg/day) * (Number of days exposure per year (100)) /365 days per year) * 35 years worked/70 year lifetime.
PPE LADD (mg/kg/day) = PPE Daily Dose (mg/kg/day) * (Number of days exposure per year (100)) /365 days per year) * 35 years worked/70 year lifetime.

[e] Baseline Total Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where $Q_1^* = 6.11e^{-2}$ (mg/kg/day).
PPE Total Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where $Q_1^* = 6.11e^{-2}$ (mg/kg/day).

For wax treatment the exposure estimate derived in lieu of data should be considered to be very conservative for the following reasons: (1) it was assumed that all of the imazalil on the treated surface could be transferred to the skin. The chemical is usually part of a wax matrix and quantitative transfer to the skin is unlikely; (2) the transfer coefficients for the hands were obtained from a field study in which

contact with contaminated foliage was highly probable; a conveyor belt treatment line would be unlikely to have such a high degree of contact (probably restricted to fingertips only).

3.2.2 Insufficient Data

At this time, there are no data available to adequately address the return of handlers to hatchers or setters for the purpose of disposing of the used smoke canister. Frequent disinfection of equipment and air which comes in contact with the shell of the egg is required to prevent Aspergillus molds. CLINFARM EC and smoke generator is used as the last stage in hatchery equipment sanitation program after the removal of one brood and before the introduction of eggs for the next brood in setters or hatchers. Before the eggs are transferred to setters, the shelves and inside parameters of the setters or hatchers are treated with imazalil using a handheld equipment or a smoke generator. Hatchery personnel then transfer the eggs from storage room to setters after the 2 hrs REI observed. Eggs are transferred from storage room to setters via trays and placed on shelves inside the setters. Eggs stay in setters for 18 days until they are ready to be transferred to hatchers. There are no dermal contact with eggs or equipment until eggs are ready to be transferred to hatchers. While in the setters, smoke generators are used to disinfect the air or equipment. The frequency of smoke generator use depends on the severity of the problem. For this assessment, it was assumed that the smoke generator was used every day until the eggs are transferred to the hatchers. Constant air flow through the setters or hatchers mitigates any risk of post-application inhalation exposure. The hatchery workers then transfer the egg trays from the setters to a conveyed belt which transports the eggs through a mechanical vaccination machine. After being vaccinated the egg trays are moved to hatchers. Eggs stay an average of three days in the hatcher. Once the chick is hatched, the shell debris is removed through a vacuum process which requires no dermal contact. Considering the process, HED believes that there is minimal risk involved in dermal or inhalation exposure to imazalil in chicken hatcheries. Therefore no post-application inhalation or dermal risk assessment was performed for reentry following smoke generator or spraying applications in chicken hatcheries. However, based on the low vapor pressure and short half life (118 minutes) of imazalil, HED concludes that ventilation of sufficient duration could adequately mitigate re-entering workers inhalation or dermal exposures and risks following smoke generator applications. Once appropriate ventilation has occurred, HED has no reason to conclude that inhalation or dermal exposures to re-entering would be harmful to hatchery handlers.

As there is no study data available on exposure to imazalil residue on treated seed, the exposure has been estimated using the unit exposure for handling granular formulations in PHED (maximum application rate and lbs treated per day). Due to the method of seed treatment HED has determined that soil-incorporated," post-application agricultural exposure is considered to be negligible as long as the soil is not directly contacted. The exception is farmers handling treated seed. Therefore it was assumed that exposure to treated seed, which has been stored for an indefinite time before use, represented a minimal exposure hazard to the handler. An estimate of the inherent risk from treated seed was conducted for descriptive purposes using relatively conservative assumptions. The results presented in Table 10 should be used only for determining a comparative range of exposure.

Table 10: Imazalil short-term and, Intermediate-term Risk for post Application Assessment of Seed Treatment

Exposure Scenario	Baseline Dermal				Baseline Inhalation					Baseline Cancer	
	Short-term Daily Dose (mg/kg/day)[a]	Int-term Daily Dose (mg/kg/day)	Short-term MOEs[c]	Int.-term MOEs[d]	Short-term Daily Dose (mg/kg/day)[e]	intermediate-term Daily Dose (mg/kg/day)[f]	Short-term MOEs[g]	Int-term MOEs[h]	Total Dose (mg/kg/day)[i]	LADD[j]	Cancer[k]
Mixer/Loader Exposure											
Mixing/loading treated seed	8.62e-03	4.12e-03	1.86e+04	3.83e+03	2.30e-03	1.74e-03	2.46e+03	1.43e+03	1.02e-02	2.13e-04	1.30e-05
Applicator exposure											
Applying treated seed	1.02e-02	4.86e-03	1.54e+04	3.25e+03	1.44e-03	1.23e-03	3.48e+03	2.03e+03	1.16e-02	2.39e-04	1.46e-05

a Short-termDaily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg).
b intermediate-termDaily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg)*0.41.
c Short-term Dermal MOE = NOAEL (160 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
d Intermediate-term Dermal MOE = NOAEL (15.8 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
e Short-term Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (60 kg).
f Intermediate and Long-term Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (70 kg).
g Short-term Inhalation MOE = NOAEL (5 mg/kg/day)/ Short-term Daily Inhalation Dose (mg/kg/day).
h Intermediate-term Inhalation MOE = NOAEL (2.5 mg/kg/day)/ Intermediate-term Daily Inhalation Dose (mg/kg/day).
I Total Dose (mg/kg/day) =Short-term Daily Dermal Dose (mg/kg/day) + short-term Daily Inhalation Dose (mg/kg/day)
J BaselineLADD (mg/kg/day) = Total Daily Dose (mg/kg/day) * 15 /365 days per year) * 35 years worked/70 year lifetime.
K Baseline Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where Q_1* = $6.11e^{-2}$ (mg/kg/day).

APPENDIX A

SHORT- TERM AND INTERMEDIATE- TERM HANDLER EXPOSURE RISK

TABLES A1 THROUGH A5

Table A1: Occupational Handler Short, Intermediate and Long-term Exposure from Imazalil at Baseline

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Application Rate (lb ai/ gallons/lb ai/1000ft^3 lb ai/100lbs)[c]	Daily amount Treated (gallons, pounds, cubic feet)[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[f]
Mixer/Loader Exposure						
mixing/loading liquid formulation for on farm seed treatment (1)	2.9	1.2	Min 3.91e-03 lb (0.5oz) ai/100 lb for wheat and barley	12,000 lbs seed	1.36e+00	5.63e-04
			Max1.0e-2 lb (1.5oz) ai/100 lb for wheat and barley		3.48e+00	1.44e-03
mixing/loading liquid formulation for drenchers applications (2)	2.9	1.2	6.26e-03 lb ai/gallon	1200 gallons	2.18e+01	9.01e-03
mixing/loading liquid formulation for waxing equipment (3)			1.67e-02 lb ai/gallon	1600 gallons (wax)	7.70e+01	3.21e-02
mixing/loading liquid formulation fort foaming equipment (4)			1.67e-02 lb ai/gallon	No Data	No Data	No Data
mixing/loading liquid formulation for high pressure hand wand applications (5)			3.20e-04 lb ai/1000ft^3	4320 ft^3 (15 hatchers)	4.00e-03	1.66e-06
				37800 ft^3 (15 setters)	3.50e-02	1.45e-05
Applicator Exposure						
applying liquid formulation with drencher (6)	No Data	No Data	6.26e-03 lb ai/gallon	1200 gallons	No Data	No Data
applying liquid formulation in a foamer equipment (7)	No Data	No Data	1.66e-02 lb ai/gallon	1600 gallons (wax)	No Data	No Data
applying liquid formulation in a waxing equipment (8)	No data	No data	1.67e-02 lb ai/gallon	No Data	No Data	No Data
applying liquid formulation with a high pressure handwand sprayer (9)	1.8	79	3.20e-04 lb ai/1000ft^3	4320 ft^3 (15 hatchers)	2.49e-03	1.09e-04
				37800 ft^3 (15 setters)	2.18e-02	9.56e-04
handler for commercial seed-treatment equipment (10)	0.015	0.18	6.71e-03 lb ai/100 lbs sudangrass	132,000 lbs seed	1.33e-01	1.59e-03
				718,000 lbs seed	7.23e-01	8.67e-03

Table A1: Occupational Handler Short, Intermediate and Long-term Exposure from Imazalil at Baseline

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Application Rate (lb ai/ gallons/lb ai/1000ft^3 lb ai/100lbs)[c]	Daily amount Treated (gallons, pounds, cubic feet)[d]	Daily Dermal Exposure (mg/day)[e]	Daily Inhalation Exposure (mg/day)[f]
			3.91e-03 (wheat & barley) lb ai/100 lbs	132,000 lbs seed	7.74e-02	9.29e-04
				718,000 lbs seed	4.21e-01	5.05e-03
			0.01(wheat & barley) lb ai/100 lbs	132,000 lbs seed	1.98e-01	2.38e-03
				718,000 lbs seed	1.08e-01	1.29e-02
apply/light smoke canisters (11)	No data	No data	0.022 lb/1000ft^3	No Data	No Data	No Data
Mixer/Loader/Applicator						
mixing/loading and applying liquid with a commercial seed-treatment equipment (12)	0.36	1.4	6.72e-03 sudangrass lb ai/100 lbs	132,000 lbs seed	3.19e+00	1.24e-02
				718,000 lbs seed	1.74e+01	6.74e-02
			3.91e-03 wheat & barley lb ai/100 lbs	132,000 lbs seed	1.86e+00	7.23e-03
				718,000 lbs seed	1.01e+01	3.93e-02
			1.0 e-02 wheat & barley lb ai/100 lbs	132,000 lbs seed	4.75e+00	1.85e-02
				718,000 lbs seed	2.58e+01	1.01e-01
mixing/loading and applying liquid with an on farm seed-treatment equipment (13)	See PPE	See PPE	Min 3.91e-03 lb (0.5oz) ai/100 lb for wheat and barley	12,000 lbs seed	See PPE	See PPE
			Max1.0e-2 lb (1.5oz) ai/100 lb for wheat and barley			

[a] Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading.

[b] Baseline inhalation exposure represents no respirator.

[c] Application rates are maximum rate values found on imazalil labels.

[d] Daily amount treated values are from the EPA HED and registrant estimates of pounds treated, cubic footage, or gallons that could be treated in a single day for each exposure scenario of concern.

[e] Daily dermal exposure (mg/day) = Unit Exposure (mg/lb ai) * Appl. rate (lb ai/1000 ft^3, lb ai/100 lb or lb ai/100 gallons) * amount (pounds treated, cubic footage or gallons) treated per day.

[f] Daily inhalation exposure (mg/day) = Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion * Application Rate (lb ai/1000 ft^3, lb ai/100 lb or lb ai/100 gallons) * amount (pounds, cubic footage or gallons) treated per day.

TableA2: Occupational Handler Short, Intermediate and Long-term Risks from Imazalil at Baseline

Exposure Scenario (Scenario #)	Baseline Dermal					Baseline Inhalation				
	Short-term Daily Dose (mg/kg/day)[a]	Intermediate, long-term Daily Dose (mg/kg/day)[b]	Short-term MOEs[c]	Int.-term MOEs[d]	Long-term MOEs[e]	Short-term Daily Dose (mg/kg/day)[f]	Long and Intermediate-term Daily Dose (mg/kg/day)[g]	Short-term MOEs[h]	Int.-term MOEs[i]	Long- term MOEs[j]
Mixer/Loader Exposure										
mixing/loading liquid formulation for on farm seed treatment (1)	1.94e-02	NA	8.25e+03	NA	NA	9.38e-06	NA	5.33+05	NA	NA
	4.97e-02	NA	3.20e+03	NA	NA	2.40e-05	NA	2.08e+05	NA	NA
mixing/loading liquid formulation for drenchers applications (2)	NA	1.28e-01	NA	1.24e+02	NA	1.50e-04	1.29e-04	NA	1.94e+04	NA
mixing/loading liquid formulation for waxing equipment (3)	NA	4.54e-01	NA	3.48e+01	NA	5.32e-04	4.58e-04	NA	5.46e+03	NA
mixing/loading liquid formulation for foaming equipment (4)	NA	No Data	NA	No Data	No Data	NA	No Data	NA	No Data	NA
mixing/loading liquid formulation for high pressure hand wand applications (5)	NA	2.35e-05	NA	NA	1.06e+05	NA	2.37e-08	NA	NA	1.05e+07
	NA	2.05e-04	NA	NA	1.22e+04	NA	2.07e-07	NA	NA	1.21e+07
Applicator Exposure										
applying liquid formulation with drencher (6)	NA	No Data	NA	No Data	No Data	NA	No Data	NA	No Data	NA
applying liquid formulation in a foamer equipment (7)	NA	No Data	NA	No Data	No Data	NA	No Data	NA	No Data	NA
applying liquid formulation in a waxing equipment (8)	NA	No Data	NA	No Data	No Data	NA	No Data	NA	No Data	NA

TableA2: Occupational Handler Short, Intermediate and Long-term Risks from Imazalil at Baseline

Exposure Scenario (Scenario #)	Baseline Dermal					Baseline Inhalation				
	Short-term Daily Dose (mg/kg/day)[a]	Intermediate, long-term Daily Dose (mg/kg/day)[b]	Short-term MOEs[c]	Int.-term MOEs[d]	Long-term MOEs[e]	Short-term Daily Dose (mg/kg/day)[f]	Long and Intermediate-term Daily Dose (mg/kg/day)[g]	Short-term MOEs[h]	Int.-term MOEs[i]	Long- term MOEs[j]
applying liquid formulation with a high pressure handwand sprayer (9)	NA	1.45e-05	NA	NA	1.72e+05	NA	1.55e-06	NA	NA	1.61e+05
	NA	1.28e-04	NA	NA	1.95e+04	NA	1.37e-05	NA	NA	1.83e+04
handler for commercial seed-treatment equipment (10)	1.90e-03	NA	8.43e+04	NA	NA	2.66e-05	NA	1.88e+05	NA	NA
	1.03e-02	NA	1.55e+04	NA	NA	1.45e-04	NA	3.46e+04	NA	NA
	1.06e-03	NA	1.45e+05	NA	NA	1.55e-05	NA	3.23e+05	NA	NA
	6.01e-03	NA	2.66e+04	NA	NA	8.42e-05	NA	5.94e+04	NA	NA
	2.83e-03	NA	5.66e+04	NA	NA	3.96e-05	NA	1.26e+05	NA	NA
	1.54e-03	NA	1.04e+05	NA	NA	2.15e-04	NA	2.32e+04	NA	NA
apply/light smoke canisters (11)	NA	No Data	NA	NA	No Data	No Data	No Data	No Data	No Data	No Data
Mixer/Loader/Applicator Exposure										
mixing/loading and applying liquid with a commercial seed-treatment equipment (12)	4.56e-02	NA	3.51e+03	NA	NA	2.07e-04	NA	2.42e+04	NA	NA
	2.49e-01	NA	6.46e+02	NA	NA	1.12e-03	NA	4.45e+03	NA	NA
	2.66e-02	NA	6.03e+03	NA	NA	1.20e-04	NA	4.15e+04	NA	NA
	1.44e-01	NA	1.11e+03	NA	NA	6.55e-04	NA	7.63e+03	NA	NA
	6.79e-02	NA	2.36e+03	NA	NA	3.08e-04	NA	1.62e+04	NA	NA
	3.69e-01	NA	4.33e+02	NA	NA	1.68e-03	NA	2.98e+03	NA	NA
mixing/loading and applying liquid with an on farm seed-treatment equipment (13)	See PPE	See PPE	See PPE	See PPE	NA	See PPE	See PPE	See PPE	See PPE	See PPE

[a] Short-term Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg).

[b] Intermediate and Long-term Daily dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg).*0.41
[c] Short-term Dermal MOE = NOAEL (160 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
[d] Intermediate-term Dermal MOE = NOAEL (15.8 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
[e] Long-term Dermal MOE = NOAEL (2.5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
[f] Short-term Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (60 kg).
[g] Long and intermediate-term Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (70 kg).
[h] Short-term Inhalation MOE = NOAEL (5 mg/kg/day)/ Short-term Daily Inhalation Dose (mg/kg/day).
[I] Intermediate-term Inhalation MOE = NOAEL (2.5 mg/kg/day)/ Intermediate-term Daily Inhalation Dose (mg/kg/day).
[J] long-term Inhalation MOE = NOAEL (2.5 mg/kg/day)/Long-tern Daily Inhalation Dose (mg/kg/day).

Table A3: Occupational Handler Short-term ,Intermediate and Long-term exposure from Imazalil at PPE

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Application Rate [c] lb ai/ gallons/lb ai/1000ft^3 lb ai/100lbs	Daily amount Treated[d] (gallons, pounds, cubic feet)	Daily Dermal Exposure (mg/day)e	Daily Inhalation Exposure (mg/day)[f]
Mixer/Loader Exposure						
Mixing/loading liquid formulation for on farm seed treatment (1)	0.023	1.2	Min 3.91e-03 lb (0.5oz) ai/100 lb for wheat and barley	12,000 lbs seed	NA	NA
			Max1e-2 lb (1.5oz) ai/100 lb for wheat and barley		NA	NA
mixing/loading liquid formulation for drenchers applications (2)			6.26e-03 lb ai/gallon	1200 gallons	NA	NA
mixing/loading liquid formulation for waxing equipment (3)			1.66e-02 lb ai/gallon	1600 gallons (wax)	6.11e-01	NA
mixing/loading liquid formulation fort foaming equipment (4)			1.67e-02 lb ai/gallon	No Data	No Data	No Data
mixing/loading liquid formulation for high pressure hand wand applications (5)			3.20e-04 lb ai/1000ft^3	4320 ft^3 (15 hatchers)	NA	NA
				37800 ft^3 (15 setters)	NA	NA
Applicator Exposure						
applying liquid formulation with drencher (6)	No Data	No Data	6.26e-03 lb ai/gallon	1200 gallons	No Data	No Data
applying liquid formulation in a foamer equipment (7)	No Data	No Data	1.66e-02 lb ai/gallon	1600 gallons (wax)	No Data	No Data
applying liquid formulation in a waxing equipment (8)	No Data	No Data	1.67e-02 lb ai/gallon	No Data	No Data	No Data
applying liquid formulation with a high pressure handwand sprayer (9)	1.8	79	3.20e-04 lb ai/1000ft^3	4320 ft^3 (15 hatchers)	NA	NA
				37800 ft^3 (15 setters)	NA	NA
handler for commercial seed-treatment equipment (10)	0.015	0.18	6.71e-03 lb ai/100 lbs sudangrass	132,000 lbs seed	NA	NA
				718,000 lbs seed	NA	NA

Table A3: Occupational Handler Short-term ,Intermediate and Long-term exposure from Imazalil at PPE

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Application Rate [c] lb ai/ gallons/lb ai/1000ft^3 lb ai/100lbs	Daily amount Treated[d] (gallons, pounds, cubic feet)	Daily Dermal Exposure (mg/day)e	Daily Inhalation Exposure (mg/day)[f]
			3.91e-03 (wheat & barley) lb ai/100 lbs	132,000 lbs seed	NA	NA
				718,000 lbs seed	NA	NA
			0.01(wheat & barley) lb ai/100 lbs	132,000 lbs seed	NA	NA
				718,000 lbs seed	NA	NA
apply/light smoke canisters (11)	No Data	No Data	0.022 lb/1000ft^3	No Data	No Data	No Data
Mixer/Loader/Applicator						
mixing/loading and applying liquid with a commercial seed-treatment equipment (12)	0.36	1.4	6.72e-03 sudangrass lb ai/100 lbs	132,000 lbs seed	NA	NA
				718,000 lbs seed	NA	NA
			3.91e-03 wheat & barley lb ai/100 lbs	132,000 lbs seed	NA	NA
				718,000 lbs seed	NA	NA
			1.0 e-02 wheat & barley lb ai/100 lbs	132,000 lbs seed	NA	NA
				718,000 lbs seed	NA	NA
mixing/loading and applying liquid with an on farm seed-treatment equipment (13)	10.4	2.4	Min 3.91e-03 lb (0.5oz) ai/100 lb for wheat and barley	12,000 lbs seed	4.88e+00	1.13e-03
			Max1e-02 lb (1.5oz) ai/100 lb for wheat and barley		1.25e+01	2.88e-03

[a] PPE dermal unit exposure represents long pants, long sleeved shirt, gloves, open mixing/loading.

[b] PPE inhalation exposure represents no respirator.

[c] Application rates are maximum rate values found on imazalil labels.

[d] Daily amount treated values are from the EPA HED and registrant estimates of pounds treated, cubic footage, or gallons that could be treated in a single day for each exposure scenario of concern.

[e] Daily dermal exposure (mg/day) = Unit Exposure (mg/lb ai) * Appl. rate (lb ai/1000 ft^3, lb ai/100 lb or lb ai/100 gallons) * amount (pounds treated, cubic footage or gallons) treated per day.

[f] Daily inhalation exposure (mg/day) = Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion * Application Rate (lb ai/1000 ft^3, lb ai/100 lb or lb ai/100 gallons) * amount (pounds, cubic footage or gallons) treated per day.

TableA4: Occupational Handler Short, Intermediate and Long-term Risks from Imazalil at PPE

Exposure Scenario (Scenario #)	Baseline Dermal					Baseline Inhalation				
	Short-term Daily Dose (mg/kg/day)[a]	Intermediate, long-term Daily Dose (mg/kg/day)[b]	Short-term MOEs[c]	Int.-term MOEs[d]	Long-term MOE,s[e]	Short-term Daily Dose (mg/kg/day)[f]	Long and Intermediate-term Daily Dose (mg/kg/day)[g]	Short-term MOEs[h]	Int.-term MOEs[i]	Long- term MOEs[j]
Mixer/Loader Exposure										
mixing/loading liquid formulation for on farm seed treatment (1)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
mixing/loading liquid formulation for drenchers applications (2)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
mixing/loading liquid formulation for waxing equipment (3)	NA	3.57e-03	NA	4.52e+03	NA	NA	NA	NA	NA	NA
mixing/loading liquid formulation for foaming equipment (4)	NA	No Data	NA	No Data	NA	NA	No Data	NA	No Data	NA
mixing/loading liquid formulation for high pressure hand wand applications (5)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Applicator Exposure										
applying liquid formulation with drencher (6)	NA	No Data	NA	No Data	NA	NA	No Data	NA	No Data	NA
applying liquid formulation in a foamer equipment (7)	NA	No Data	NA	No Data	NA	NA	No Data	NA	No Data	NA
applying liquid formulation in a waxing equipment (8)	NA	No Data	NA	No Data	NA	NA	No Data	NA	No Data	NA

TableA4: Occupational Handler Short, Intermediate and Long-term Risks from Imazalil at PPE

Exposure Scenario (Scenario #)	Baseline Dermal					Baseline Inhalation				
	Short-term Daily Dose (mg/kg/day)[a]	Intermediate, long-term Daily Dose (mg/kg/day)[b]	Short-term MOEs[c]	Int.-term MOEs[d]	Long-term MOE,s[e]	Short-term Daily Dose (mg/kg/day)[f]	Long and Intermediate-term Daily Dose (mg/kg/day)[g]	Short-term MOEs[h]	Int.-term MOEs[i]	Long- term MOEs[j]
applying liquid formulation with a high pressure handwand sprayer (9)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
handler for commercial seed-treatment equipment (10)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
apply/light smoke canisters (11)	NA	No Data	NA	NA	No Data	NA	No Data	NA	NA	No Data
Mixer/Loader/Applicator Exposure										
mixing/loading and applying liquid with a commercial seed-treatment equipment (12)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
mixing/loading and applying liquid with an on farm seed-treatment equipment (13)	6.97e-02	NA	2.30e+03	NA	NA	1.88e-05	NA	2.65e+05	NA	NA
	1.79e-01	NA	8.96e+02	NA	NA	4.80e-05	NA	1.04e+05	NA	NA

[a] Short-term Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg).

[b] Intermediate and Long-term Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg)*0.41.
[c] Short-term Dermal MOE = NOAEL (160 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
[d] Intermediate-term Dermal MOE = NOAEL (15.8 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
[e] Long-term Dermal MOE = NOAEL (2.5 mg/kg/day)/ Daily Dermal Dose (mg/kg/day).
[f] Short-term Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (60 kg).
[g] Long and intermediate-term Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (70 kg).
[h] Short-term Inhalation MOE = NOAEL (5 mg/kg/day)/ Short-term Daily Inhalation Dose (mg/kg/day).
[I] Intermediate-term Inhalation MOE = NOAEL (2.5 mg/kg/day)/ Intermediate-term Daily Inhalation Dose (mg/kg/day).
[J] long-term Inhalation MOE = NOAEL (2.5 mg/kg/day)/Long-tern Daily Inhalation Dose (mg/kg/day).

Table A5: Exposure Scenario Descriptions for the Use of Imazalil			
Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader Descriptors			
Mixing/loading liquid formulation for on farm seed treatment (1)	PHED v. 1.1	12,000 lbs wheat or barley seed (100 acres planted at 120 lbs per acre)	**Baseline:** Hand, dermal, and inhalation data are AB grades. Hand = 72 to 122 replicates; dermal = 53 replicates; and inhalation = 85 replicates. High confidence in hand/dermal and inhalation data. No protection factor was needed to define the unit exposure value. **PPE:** The same dermal data are used as for the baseline coupled with a 98% protection factor to account for gloves. Hands = AB grades. Hands = 59 replicates. High confidence in hands, dermal data.
Mixing/loading liquid (EC) for Drencher application (2)	PHED v. 1.1	1,200 gallons Based on treating 2 trucks. Each truck contains 60 bins and the uptake for each bin in 1 gallon.	
Mixing/loading liquid (EC) for a waxing equipment (3)	PHED v. 1.1	1,600 gallons Based on treating 16000 boxes of citrus (90 lbs per box) the uptake is 1 gallon per 10 boxes	
Mixing/loading liquid (EC) for a foaming equipment (4)	PHED v. 1.1	No Data	
Mixing/loading liquid formulation for high pressure hand application (5)	PHED v. 1.1	37,800 ft^3 for 15 hatchers and 4,320 ft^3 for 15 setters	
Applicator			
Applying liquid formulation with a drencher (6)	No Data	1,200 gallons Based on treating 2 trucks. Each truck contains 60 bins and the uptake for each bin in 1 gallon.	No Data
Applying liquid formulation for a foaming equipment (7)	No Data	1,600 gallons Based on treating 16000 boxes of citrus (90 lbs per box) the uptake is 1 gallon per 10 boxes	
Applying liquid formulation for a waxing equipment (8)	No Data	No Data	
Applying liquid formulation with a high pressure handwand sprayer (9)	PHED v. 1.1	37800 ft^3 for 15 hatchers and 4320 ft^3 for 15 setters	**Baseline:** Dermal = AB grades, inhalation = A grade. Dermal = 7-13 replicates; inhalation = 13 replicates. Gloved data was used to calculate the no gloved hand data, assuming gloves provide 90% protection. Hands = C grade with 13 replicates. Low confidence in hand, dermal, and inhalation data. Baseline data includes use of chemical-resistant gloves.
Handler for commercial seed treatment (10)	Uniroyal Data MRID # 447315-01	min 132,000 lbs of seed (based on wheat) 7.5 tons/hr max 718, 000 lbs of seed (based on wheat) 40.8 tons/hr	See Study Review; based on geometric mean of data and "typical" volume of seed handled per day.
Apply/light smoke canisters (11)	No data	No Data	No Data
Mixer/Loader/applicator			

Table A5: Exposure Scenario Descriptions for the Use of Imazalil			
Exposure Scenario (Number)	Data Source	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixing/loading and applying liquid with a commercial seed-treatment equipment (12)	Uniroyal Data MRID # 447315-01	min 132,000 lbs of seed (based on wheat) 7.5 tons/hr max 718, 000 lbs of seed (based on wheat) 40.8 tons/hr	See Study Review; based on geometric mean of data and "typical" volume of seed handled per day.
Mixing/loading/applying seed treatment (dry) in planter box for on- farm seed treatment (13)	Fenske Study data	12,000 lbs wheat or barley seed (100 acres planted at 120 lbs per acre) .	All data were for gloved hands; seed treatment only, not planting; 60 replicates (see study).

[a] All *Standard Assumptions* are based on an 8-hour work day as estimated by HED and registrant.

[b] All handler exposure assessments in this document are based on the "Best Available" data as defined by the PHED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments). Best available grades are assigned to data as follows: matrices with A and B grade data (i.e., Acceptable Grade Data) and a minimum of 15 replicates; if not available, then all data regardless of the quality (i.e., All Grade Data) and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor. Generic data confidence categories are assigned as follows:

High = grades A and B and 15 or more replicates per body part
Medium = grades A, B, and C and 15 or more replicates per body part
Low = any run that included D or E grade data or has less than 15 replicates per body part

APPENDIX B

OCCUPATIONAL HANDLER INTERMEDIATE AND LONG -TERM CANCER (Q^*) RISKS

TABLE B

Table B: Occupational Handler Short, Intermediate and long-term Cancer (Q*) Risk for Imazalil									
Exposure Scenario (Scen. #)	Range of Application Rates (lb ai/A)[a]	Amount Handled per Day[b]	Number of Exposures per Year[c]	Baseline Total Daily Dose (mg/kg/day)[d]	Baseline LADD (mg/kg/day)[e]	Baseline Total Cancer Risk[f]	PPE Total Daily Dose (mg/kg/day)[g]	PPE LADD (mg/kg/day)[h]	PPE Total Cancer Risk[i]
Mixer/Loader Risk									
Mixing/loading liquid formulation for on farm seed treatment (1)	0.00391 lb/100 lb	12,000 lbs	10/15	1.94e-02	2.66e-04 4.0e-04	1.62e-05 2.44e-05	1.64e-04	2.24e-06 3.36e-06	1.37e-07 2.05e-07
	0.01 lb/100 lbs		10/15	4.97e-02	6.81e-04 1.02e-03	4.16e-05 6.24e-05	4.18e-04	5.73e-06 8.59e-06	3.50e-07 5.25e-07
Mixing/Loading Liquid (EC) for Drencher application (2)	0.6255 lb ai/100 gallons	1200 gallons	100	1.28e-01	1.75e-02	1.07e-03	1.14e-03	1.56e-04	9.55e-06
Mixing/Loading Liquid (EC) for a waxing equipment (3)	1.665 lb ai/100 gallons	1600 gallons	100	4.54e-01	6.22e-02	3.80e-03	4.06e-03	5.56e-04	3.40e-05
Mixing/Loading Liquid (EC) for a foaming equipment (4)	1.665 lb ai/100 gallons	No data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
mixing/loading liquid formulation for high pressure hand application (5)	0.00032 lb ai/1000 ft^3	4320 ft^3	250	2.35e-05	8.05e-06	4.92e-07	NA	NA	NA
		37800 ft^3	250	2.06e-04	7.04e-05	4.30e-06	NA	NA	NA
Applicator									
Applying liquid formulation with a drencher (6)	0.6255 lb ai/100 gallons	1200 gallons	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Applying liquid formulation for a foaming equipment (7)	1.665 lb ai/100 gallons	1600 gallons	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Applying liquid formulation for a waxing equipment (8)	1.665 lb ai/100 gallons	No data	No Data	NO Data	No data	No Data	NO Data	No Data	No Data
Applying liquid formulation with a high pressure handwand sprayer (9)	0.00032 lb ai/1000	4320ft^3	250	1.61e-05	5.50e-06	3.36e-07	NA	NA	NA
		37800 ft^3	250	1.41e-04	4.83e-05	2.95e-06	NA	NA	NA
Handler for commercial seed treatment (10)	0.00671 lb ai/100 lbs Sudangrass	132,000	15	1.92e-03	3.95e-05	2.42e-06	3.05e-04	6.27e-06	3.83e-07
		718,000	15	1.05e-02	2.15e-04	1.31e-05	1.66e-03	3.41e-05	2.08e-06
	Min 0.00396 lb ai/100lb Wheat and barley	132,000	15	1.08e-03	2.21e-05	1.35e-06	1.78e-04	3.65e-06	2.23e-07
		718,000	15	6.10e-03	1.25e-04	7.66e-06	9.67e-04	1.99e-05	1.21e-06

Table B: Occupational Handler Short, Intermediate and long-term Cancer (Q*) Risk for Imazalil									
Exposure Scenario (Scen. #)	Range of Application Rates (lb ai/A)[a]	Amount Handled per Day[b]	Number of Exposures per Year[c]	Baseline Total Daily Dose (mg/kg/day)[d]	Baseline LADD (mg/kg/day)[e]	Baseline Total Cancer Risk[f]	PPE Total Daily Dose (mg/kg/day)[g]	PPE LADD (mg/kg/day)[h]	PPE Total Cancer Risk[i]
	Max 0.01lb ai/100 lbs wheat and barley	132,000	15	2.87e-03	5.89e-05	3.60e-06	4.54e-04	9.34e-06	5.71e-07
		718,000	15	1.56e-02	3.61e-04	2.20e-06	2.47e-03	5.08e-05	3.10e-06
Apply/light smoke canisters (11)	0.022 lb ai/1000 ft^3	No data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Mixer/ Loader/Applicator									
Mixing/loading and applying liquid with a commercial seed-treatment equipment (12)	0.00671 lb ai/100 lbs Sudangrass	132,000	15	4.58e-02	9.40e-04	5.74e-05	8.18e-03	1.68e-04	1.03e-05
		718,000	15	2.49e-01	5.14e-03	3.14e-04	4.45e-02	9.14e-04	5.58e-05
	Min 0.00396 lb ai/100lb Wheat and barley	132,000	15	2.67e-02	5.48e-04	3.35e-05	4.77e-03	9.79e-05	5.98e-06
		718,000	15	1.45e-01	2.98e-03	1.82e-04	2.59e-02	5.33e-04	3.25e-05
	Max 0.01lb ai/100 lbs wheat and barley	132,000	15	6.82e-02	1.40e-03	8.56e-05	1.22e-02	2.50e-04	1.53e-05
		718,000	15	3.71e-01	7.62e-03	4.66e-04	6.63e-02	1.36e-03	8.32e-05
Mixing/Loading/Applying as a Seed Treatment (dry) in planter box for on farm seed treatment (13)	0.00391 lb/100 lb	12,000	10/15	See PPE	See PPE	See PPE	6.97e-02	9.55e-04 1.43e-03	5.84e-05 8.75e-05
	0.01 lb/100 lbs		10/15	See PPE	See PPE	See PPE	1.79e-01	2.45e-03 3.68e-03	1.50e-04 2.25e-04

[a] Application rates are maximum rate values found on imazalil labels.

[b] Daily amount treated values are from the EPA HED and registrant estimates of pounds treated, cubic footage, or gallons that could be treated in a single day for each exposure scenario of concern.

[c] Number of days exposed to imazalil are assessed as follows:
(1,13) For on farm seed treatment 10 days for private applicator and 15 days for commercial applicator
(10,12) For commercial seed treatment facility workers are exposed for 15 days
(2,3) For post harvest treatment of citrus 100 days per year
(5,9) For egg hatcheries 250 days

[d] Baseline Total Daily Dose = Baseline dermal daily dose+ base line Intermediate-term inhalation daily dose

[e] Baseline LADD (mg/kg/day) = Baseline Total Daily Dose (mg/kg/day) * (Number of days exposed per year /365 days per year) * 35 years worked/70 year lifetime.

[f] Baseline Total Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where Q_1* = $6.11e^{-2}$ (mg/kg/day).

[g] PPE Total Daily Dose = PPE dermal daily dose+ PPE Intermediate-term inhalation daily dose

[h] PPE LADD (mg/kg/day) = PPE Total Daily Dose (mg/kg/day) * (Number of days exposed per year /365 days per year) * 35 years worked/70 year lifetime.

i PPE Total Cancer Risk = Baseline LADD (mg/kg/day) * (Q_1*), where Q_1* = $6.11e^{-2}$ (mg/kg/day).

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